

**Steps taken following Prequalification of [MA057 trade name]\***

<b>Changes</b>	<b>WHOPAR parts affected</b>	<b>Accepted on</b>
Change in the shelf life of the FPP	4	08 July 2010
Change in the name of the FPP supplier	3,4,5	17 September 2017
Change in labelling information to delete the street name of the FPP supplier	5	17 September 2017
Product information updated with respect to section 4 of the SmPC and PIL	3,4	02 September 2018
Requalification	3,4	21 September 2018
Product information updated with respect to section 4 of the SmPC and PIL	3,4	August 2021
Change in the address of the manufacturer of the FPP	3,6,7	August 2021
Requalification	1	7 February 2025
General update of the WHOPAR to reflect the current WHOPAR structure, product specifics, WHO guidelines and state of scientific knowledge	3,4,5	March 2025

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\* Trade names are not prequalified by WHO. This is the national medicines regulatory authority's responsibility.